



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,483	08/24/2001	Fabrice Duprat	1201-CIP-DIV-2-00	3851

35811 7590 10/13/2005

IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP
1650 MARKET ST
SUITE 4900
PHILADELPHIA, PA 19103

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,483

Applicant(s)

DUPRAT ET AL.

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☒ Certified copies of the priority documents have been received in Application No. 08/749816.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1632

DETAILED ACTION

Applicant's reply dated 09/06/2005 has been received. Claims 1-31 and 33 are cancelled. Claim 32 has been amended, is pending and is under consideration in the instant office action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 USC 120 as follows:

An application in which benefits of an earlier application are desired must contain a specific reference to the prior applications in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The current status of all nonprovisional parent applications referenced should be included or updated. The current reference, filed with the application transmittal sheets dated 08/24/2001 does not include that US Patent Application Serial Number 09/144914 has issued as US Patent No. 6,309,855, dated 10/30/2001 or that US Patent Application Serial Number 09/144914 has issued as US Patent No. 6,013,470, dated 01/11/2000.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1632

Claim 32 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record set forth at pages 2-7 of the previous office action dated 03/08/2005 as reiterated below.

Applicant's arguments have been fully considered and are found partially persuasive.

The claim was previously rejected on 3 grounds. First, the claim was rejected because it fails to recite a phenotype and therefore encompasses a transgenic knockout mouse lacking the genomic sequence encoding SEQ ID NO:5 wherein the mouse exhibits any phenotype (see pages 5-6 of the previous office action dated 11/28/2003). The second grounds of the rejection was based in the claims broadly encompassing the knockout of any gene that indirectly affects expression of the gene product set forth by SEQ ID NO:5 as opposed to the disruption of the gene that encodes a polypeptide comprising SEQ ID NO:5 (see pages 5-6 of the previous office action dated 03/08/2005). The third grounds of the rejection was on the basis that the claims broadly encompass chimeric mice (pages 6-7 of the previous office action dated 03/08/2005).

The second and third aspects of the rejection are withdrawn in light of Applicant's amendments to the claim.

However, the rejection of the claim is maintained on the first grounds listed above, as set forth below.

Applicant has argued the specification teaches that the cloning of TASK should help identify agents that will block potassium channels and that a phenotype need not be identified in the claim to the knockout mouse. Applicant asserts that the cloning of a new member of a potassium channel family provides new means for screening for pharmaceutical modulators of the channels that could be used to treat unidentified, associated diseases. Applicant argues that

Art Unit: 1632

the claimed mouse can be used to screen for agents that block the potassium channel comprising SEQ ID NO:5 (page 4, paragraph 4 of Applicant's Remarks). Applicant argues that the knockout mouse can be used as a control in selecting potential therapeutic agents (see page 5 of Applicant's remarks).

In response, as set forth in the previous office action dated 03/08/05, the claims are so broad as to encompass any phenotype. The skilled artisan would not know how to make the claimed mouse such that it exhibits any one of, or any combination of, phenotypes encompassed by the claim. The phenotype of the claimed mouse is not limited. Furthermore, the specification fails to teach a phenotype for the claimed mouse so the skilled artisan would not know what phenotype to assess in using the mouse to screen pharmaceuticals as asserted by Applicant. Because the specification has not taught the phenotype of the mouse, one of skill in the art could not predict whether the claimed mouse would exhibit lethality, infertility, spontaneous seizures, rapid heartbeat, or perhaps no observable phenotype at all. It is not known if, or how, the claimed mouse differs from wild-type. Without a recitation of a phenotype in the claim, the skilled artisan would not know when they had attained the claimed mouse nor would they know how to use it without further undue experimentation to reveal an assessable phenotype.

Applicant refers to the Linden et al Abstract submitted 02/04/2005 as teaching the use of a knockout mouse that lacks a phenotype. In response, how Applicant's remarks apply to Linden et al is unclear. Linden et al taught the phenotypic characterization of a Task-1 knockout mouse and assays used to uncover or reveal a phenotypic effect of the gene disruption. Agents were administered to the knockout mouse to determine if removal of the gene product has an effect on the response of the mouse to the agent. For example, Linden et al were assessing the effects of

Art Unit: 1632

isofluorane on the TASK-1 knockout mouse. In this instance, the knockout was not a control; it was the experimental group. This does not correlate with Applicant's asserted use of the claimed mouse as a control to screen for pharmaceutical agents that treat disease wherein the agent normally modulates the gene that is knocked out in the control mouse. Therefore, it is maintained that the specification fails to teach how to make or use the claimed mouse exhibiting any phenotype, including wild-type, as encompassed by the claims.

Art Unit: 1632

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

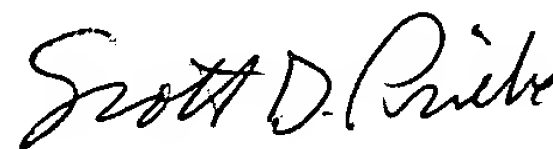
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER